

REMARKS

The Examiner's Office action dated June 14, 2005, has been reviewed. Claims 1-71 are pending in this application. Applicant has cancelled claims 1-44 and withdrawn claims 45-55 and 67-71. Claims 56, 62, and 63 have been amended herein. In view of these Amendments and the following arguments, Applicant respectfully submits that the application is in condition for allowance.

Election/ Restriction Requirement.

The Examiner made a restriction requirement between Group I (claims 1-44), Group II (Claims 45-55), Group III (Claims 56-66), and Group IV (Claims 67-71) in the June 14, 2005 Office action. There are 71 claims in the application. Applicant provisionally elected to prosecute claims 1-44 and 56-66 with traverse during a telephone conversation with the Examiner. At the time of the telephone conversation, Applicant's Representative understood the claims of Group I to include claims 1-44 and 56-66. In paragraph 4, page 5 of the Examiner's Office action the Examiner indicated that Group I included claims 1-44 and 56-66. Applicant has canceled claims 1-44. Thus, Applicant elects to prosecute, without traverse, claims 56-66 in this application.

Rejections under 35 U.S.C. § 112, first paragraph.

The Examiner rejected claims 1-44 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description and enablement requirements. As previously discussed, the Examiner indicated that Group I comprises claims 1-44 and 56-66. (See in paragraph 4 of the June 14, 2005, Office action.) Accordingly, Applicant will treat claims 56-66 as though they were examined with now canceled claims 1-44 and rejected on the same bases. The Examiner stated the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention at the time the application was filed. The Examiner further rejected the claims under Section 112, first paragraph, because the claims contained subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the invention. Applicant respectfully requests reconsideration of these rejections.

The Examiner's rejection relates to how the claimed nanospheres are prepared. Applicant submits that one skilled in the art would appreciate how to make the claimed nanosphere upon reviewing the specification of the subject application and respectfully requests reconsideration of this rejection.

A process for preparing the above referenced nanospheres is disclosed in paragraphs 41-46. Figure 6 shows the spray drying system 50 used to prepare the claimed nanospheres comprised of nanoparticles. A feed stock comprising magnetically responsive nanoparticles is atomized in an aerosol distribution using an ultrasonic liquid atomization spray nozzle and dried within a drying chamber 56. As the nanoparticles are dried, the solvent, is evaporated and the nanoparticles agglomerate as a function of their physical characteristics. One of skill in the art understands that as an atomized droplet is dried, the particles present therein will be forced together. This occurs because of the particles' natural tendency to form a structure having the smallest surface area – a sphere – as the solvating media is dried off of the droplet. Formation of the nanospheres in this manner is further discussed in paragraph 39. A 12,000x magnified photo of a nanosphere formed in the above-described manner is attached hereto as Exhibit "1".

Applicant's claims recite a nanosphere having either a bio-compatible or bioerodable shell. The materials used to form the bio-compatible or bioerodable shell are discussed in paragraphs 13 and 21 and may include silica, collagen, albumin or polylactic acid. As discussed in paragraphs 41-46, the starting feed stock may contain the material used to form the bio-compatible or bioerodable shell in desired concentrations. One skilled in the relevant art will appreciate that as atomized droplets of the feed stock are dried in the drying chamber 56, the nanoparticles agglomerate and the bio-compatible or bioerodable shell material is forced from between the nanoparticles to form such bio-compatible or bioerodable shell.

Turning now to the question of “cell adhesion factors”, such adhesion factors are disclosed in paragraphs 22 and 23 and in Table 1. One of skill in the relevant art will appreciate that the term “cell adhesion factors” is used regularly to describe the materials disclosed in the application. One of skill in the art will appreciate that cell adhesion factors are supported on the shell by the process disclosed in paragraph 46. One skilled in the art will further appreciate that certain of the cell adhesion factors described in the application are capable of binding to the materials disclosed as comprising the bio-compatible or bioerodable shell.

The Examiner requested Applicant to define the term “erodable polymer.” Applicant has cancelled claims 8, 14, and 18. Eroderable polymers are discussed in paragraph 21 of the current application.

In light of the above, Applicant respectfully submits the requirements of Section 112, first paragraph, have been satisfied and respectfully request withdrawal of the Examiner’s Section 112 rejections.

Rejections under 35 U.S.C. § 102(a).

The Examiner rejected claims 1-44 under 35 U.S.C. § 102(a) as being anticipated by pioneers in the art as disclosed by Pankhurst et al. in the article entitled “Application of magnetic Nanoparticles in Biomedicine” (hereinafter “Pankhurst”) and/or Tartaj et al. in the article “The Preparation of Magnetic Nanoparticles for Applications in biomedicine” (hereinafter “Tartaj”). The Examiner further rejected claims 1-4, 14, 23, 24, and 37 as being anticipated by Wilhelm et al. in the article entitled “Intracellular Uptake of Anionic Superparamagnetic Nanoparticles as a Function of their Surface Coating” (hereinafter “Wilhelm”). Applicant respectfully submits that claims 56-66 are not anticipated by the cited references.

For the reasons set forth above, Applicants will discuss claims 1-44 and claims 56-66 in response to the Examiner’s Section 102(a) rejection. Claims 1-44 have been cancelled herein.

Applicant's claim 56, as amended, is directed to a magnetically responsive nanosphere comprising a plurality of magnetically responsive nanoparticles and a bio-compatible shell. The nanosphere is prepared by a process comprising atomizing a nanodispersion to produce an aerosol. The nanodispersion comprises a sodium silicate and a plurality of magnetically responsive nanoparticles. Each nanoparticle has a magnetic moment. The aerosol is passed through a magnetic field to align the magnetic moments of the nanoparticles and drying the aerosol in a heated chamber. Thus, independent claim 56 requires a nanosphere having a bio-compatible shell that is prepared by atomization and drying.

Pankhurst discloses several possible uses for magnetic nanoparticles. These uses range from drug delivery to magnetic resonance imaging contrast enhancement. Pankhurst discusses nanoparticles having a biocompatible shell of silica and a functional group attached to the shell and mentions the possibility micron size agglomerates comprised of superparamagnetic particles. Pankhurst does not, however, disclose a nanosphere having a plurality of magnetically responsive nanoparticles and a bio-compatible shell prepared by atomization and drying the resulting aerosol in a heated chamber. Therefore, any Section 102(a) rejection of claim 56 in view of Pankhurst must fail.

Tartaj likewise does not anticipate Applicant's claim 56. Tartaj discloses an aerosol method of producing hollow spheres having a shell formed from small crystallites. The method of Tartaj teaches producing nanoparticles by spraying a solution into a series of reactors where the solvent is evaporated and the solute is condensed within the droplet. The precipitated particle then undergoes drying and thermolysis to produce a microporous solid which is sintered to form a dense particle. Tartaj teaches that a solution containing Fe(II) ammonium citrate may be sprayed into the reactor to form hollow spheres having a shell of small aggregated crystallites. See Tartaj at 189, left column. Thus, Tartaj teaches a hollow nanosphere wherein the nanoparticles form the outer shell. Accordingly, Tartaj does not teach or suggest a nanosphere having a plurality of magnetically responsive nanoparticles and a bio-compatible shell as taught

in Applicant's claim 56. Consequently, claim 56 is not anticipated by Tartaj, and a Section 102(a) rejection of this claim would be improper.

Wilhelm does not anticipate Applicant's independent claim 56. Wilhelm discloses a magnetite nanoparticle that is coated with albumin. The nanoparticle in Wilhelm is prepared using the Massart process. The nanoparticle is coated with bovine serum albumin. See Wilhelm section 2.2. The nanoparticle is coated by incubating the bovine serum albumin overnight in an aqueous suspension of nanoparticles. The resulting product is an albumin coated nanoparticle. Wilhelm does not, however, teach or suggest a nanosphere having a plurality of magnetically responsive nanoparticles and a bio-compatible shell as taught in Applicant's claim 56. Consequently, claim 56 is not anticipated by Wilhelm, and any Section 102(a) of this claim would be improper.

Claims 57-62 depend either directly or indirectly from claim 56 and include all of its limitations. Thus, any Section 102 rejection of claims 57-62 must likewise fail.

Applicant's independent claim 63, as amended, is directed to a magnetically responsive nanosphere. The nanosphere comprises at least one magnetically responsive nanoparticle and a bioerodable shell. The nanosphere is prepared by a process comprising atomizing a dilute solution comprising magnetically responsive nanoparticles to form an aerosol. The aerosol comprises a plurality of droplets comprising at least one magnetically responsive nanoparticle, a solvating media, and a bioerodable polymeric material. Each nanoparticle comprises a magnetic moment. The process further comprises passing the aerosol through a magnetic field to align the magnetic moments of the nanoparticles and drying the droplet in a heated chamber to remove the solvating media.

As discussed above, Pankhurst discloses several uses for magnetic nanoparticles. However, Pankhurst discloses only nanoparticles having a biocompatible shell. Pankhurst mentions only the possibility of "micron" size agglomerates comprised of superparamagnetic particles. Pankhurst does not, however, teach or suggest a nanosphere having either a magnetically responsive nanoparticle or a bioerodable shell. Further, Pankhurst does not teach a

nanosphere prepared by a process comprised of atomizing a dilute solution to form an aerosol, passing the aerosol through a magnetic field, and drying the aerosol in a heated chamber to remove the solvating media. Therefore, any Section 102(a) rejection of claim 63 in view of Pankhurst must fail.

Likewise, Tartaj does not anticipate Applicant's independent claim 63. Tartaj discloses an aerosol method of producing hollow spheres having a shell formed from small crystallites. The method of Tartaj teaches producing nanoparticles by spraying a solution into a series of reactors where the solvent is evaporated and the solute condensed within the droplet. The precipitated particle then undergoes drying and thermolysis to produce a microporous solid which is sintered to form a dense particle. Tartaj teaches that the particles are formed by spraying a solution containing Fe(II) ammonium citrate into a reactor to form hollow spheres having a shell of small aggregated crystallites. See Tartaj at 189, left column. Thus, Tartaj teaches a hollow nanosphere wherein the nanoparticles form the outer shell. Accordingly, Tartaj does not teach or suggest a nanosphere comprising at least one magnetically responsive nanoparticle and a bio-compatible shell as in Applicant's claim 63. Consequently, claim 63 is not anticipated by Tartaj, and the Section 102(a) rejection of this claim must be withdrawn.

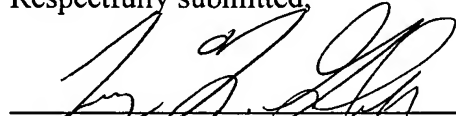
Wilhelm does not anticipate Applicant's independent claim 63. Wilhelm discloses magnetite nanoparticles that are coated with albumin. The nanoparticles in Wilhelm are prepared using the Massart process. The prepared nanoparticles are individually coated with bovine serum albumin to produce a coated nanoparticle. See Wilhelm section 2.2. The nanoparticles are coated by incubating the bovine serum albumin overnight in an aqueous suspension of nanoparticles. Wilhelm does not, however, teach or suggest a nanosphere having at least one magnetically responsive nanoparticle and a bioerodable shell prepared by atomizing a dilute solution to produce an aerosol, passing the aerosol through a magnetic field, and drying the aerosol in a heated chamber to remove the solvating media as taught in Applicant's claim 63. Consequently, claim 63 is not anticipated by Wilhelm, and any Section 102(a) of this claim would be improper.

Claims 64-66 depend either directly or indirectly from claim 63 and include all of its limitations. Thus, any Section 102 rejection of claims 64-66 should likewise fail.

The Amendments submitted herewith do not contain any new matter. Applicant respectfully submits that the application is in condition for allowance. A Notice of Allowance courteously is solicited. In the event that there are any questions or comments concerning the amendment or the application, the Examiner is invited to contact the undersigned.

This is intended to be a complete response to the Office Action mailed June 14, 2005.

Respectfully submitted,



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EXHIBIT "1"

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